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Electrocardiogram Signal Quality Comparison Between a Dry Electrode and a Standard Wet Electrode over a Period of Extended Wear

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ELECTROCARDIOGRAM SIGNAL QUALITY COMPARISON BETWEEN A DRY ELECTRODE AND A STANDARD WET ELECTRODE OVER A PERIOD OF EXTENDED WEAR

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DEDICATION

"The future belongs to those who believe in the beauty of their dreams,"

Eleanor Roosevelt.

I am very fortunate to have a long list of individuals that have stood behind me through the completion of my thesis. I will not list everyone that has been there for me during this process, however, there are a few that deserve acknowledgement for being extraordinary. These individuals stood by me through the hours of work and frustration. They stood by me lending an ear to listen to my concerns and feelings of being overwhelmed. These individuals, like myself, believed in the beauty of my dreams.

Dad, Mom, Jesse, Kurt, and Tim

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ABSTRACT

The use of a dry electrode (DE), which does not rely on electrolytic solution, may circumvent potential disadvantages of a wet electrode (WE). The accuracy of the electrocardiogram (ECG) signal, provided by the electrode, is vital. The purpose of the study was to investigate if differences in signal quality, reflected by the signal-to-noise ratio (SNR), existed between the standard gel 3M™ Red Dot™ 2560 electrode (WE) and the Orbital Research Incorporated (ORI) dry electrode (DE) over a 96 hour period of continuous wear. Assessments were made within electrode types, comparing potential signal deterioration within the electrode over time, and also between the two electrode types, comparing SNR over time.

Twenty healthy adult volunteers completed the research protocol, each simultaneously wearing the two pairs of electrodes for 96 hours continuously in a lead II configuration. ECG tracings were collected simultaneously on different telemetry channels once a day over five consecutive days. The collection period consisted of six, three minute stages. The six stages included two bouts of rest, supine and standing, followed by three submaximal exercise stages, ending with one stage of standing rest. Data collected using the telemetry unit was de-noised by Matlab™ using sixth order Daubechies wavelet transform technology.

No significant differences existed within the DE SNRs over time, indicating that SNR deterioration did not occur. Although a significant difference existed within the WE SNR between day 0 and 1 (17.83 ± 2.62 vs. 18.68 ± 2.35 on day 0 and day 1, respectively, $p < .01$) in the standing stage, the noise was reduced; therefore, SNR deterioration did not occur. The only significant difference ($p < .01$) between the WE and DE SNRs occurred on day 2 (19.94 ± 2.11 vs. 18.73 ± 1.97) and day 4 (20.16 ± 2.16 vs. 18.96 ± 2.21) in the supine stage, favoring the WE. The difference observed could be attributed to a potential loss of skin contact when in the supine position. No differences were noted at any other stage.

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CHAPTER I

INTRODUCTION

The Electrical Activity of the Myocardium

An electrocardiogram (ECG) presents valuable information regarding the electrical activity of the heart. One complete cardiac cycle, systole and diastole, is represented on the ECG by a series of waves, labeled PQRST (Figure 1). Each component of the waveform represents different ionic interactions at the membrane level. The three main waves, the P, QRS, and T waves, represent atrial depolarization (contraction), ventricular depolarization (contraction), and ventricular repolarization (relaxation), respectively.[1] Morphology, frequency and amplitude of each wave, segment, and interval is documented on the ECG recording.[2] The information provided has substantial clinical value as all components are compared to associated normal values for interpretation and any deviations in electrical behavior may be indicative of various cardiac pathologies. Of particular interest is ECG signal accuracy as the absence of such can result in decreased reliability of the test and both false negatives, overlooked abnormalities, and false positives, unwarranted diagnoses.[3] This is particularly important when considering the prevalence of heart disease and resulting fatality. According to a report from the American Heart Association (AHA), Heart Disease and Stroke Statistics 2011 Update, in 2007 coronary heart disease caused 1 in 6 deaths. The AHA also suggested that "approximately every 25 seconds, an American will have a coronary event, and approximately every minute, someone will die of one."[4] Therefore, an accurate ECG is ofthe utmost importance in order to both detect any cardiac abnormalities as well as provide valuable information regarding the location of such abnormality.

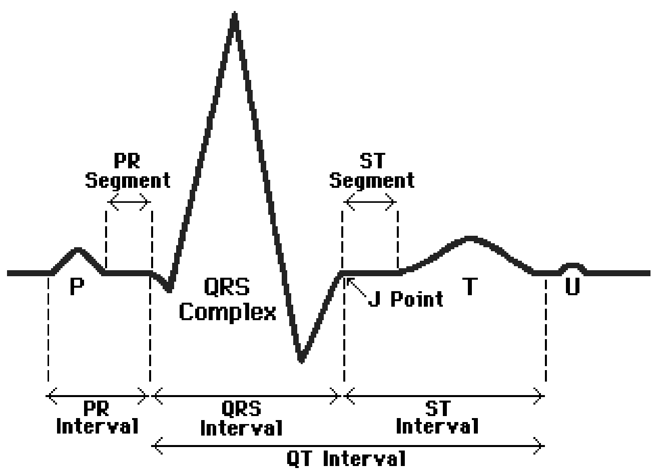

Figure 1: Components of the ECG Waveform[5]

Ionic Conduction

An understanding of ionic conductance is requisite in the discussion of the operation of electrodes and the resulting recording of the ECG. Ionic conduction refers to the intra- and extra- cellular movement of ions that produce electrical potentials and affect electrical current flow.[6] An ECG is a recording of the electrical activity in the myocardium, and therefore, is representative of its associated mechanical action. In order for the ECG to record the electrical activity produced by ionic movement in the myocardium, the bioelectrical signal, the activity must be transduced into an ECG signal. The ionic movement thus must be converted into electron movement at the electrolyte-electrode interface (i.e. wet electrode) or at the electrode-skin interface (i.e. dry electrode) and expressed as voltage on the ECG recording.[7]

The myocardium has an area of specialized cells that involuntarily generate electrical impulses, thus influencing mechanical contraction or relaxation. The myocardium's ability to generate intrinsic electricity without the stimulus of an external source is referred to as automaticity. Although specialized myocardial pacemaking cells are considered the endogenic source of the electric potential, the autonomic nervous system can modulate this. Both constituents of the autonomic nervous system, the parasympathetic nervous system and the sympathetic nervous system, can influence the frequency at which the impulses are generated.[1]

As previously established, ionic conduction dictates the electrical activity, and therefore the mechanical action of the myocardium. The mechanical activity of the myocardium is dictated by the movement of three ions, Na^+, Ca^{2+}, and K^+. A charge differential exists under resting conditions between the interior and exterior of the myocytes. This differential is maintained through the simultaneous and controlled release of Na^+ ions and the simultaneous and controlled entrance of K^+ ions into the cell through the use of the Na^+/K^+ ATPase pump. Ions are only able to circulate into or out of myocytes through the use of channels, as each myocyte's membrane is impermeable. The impermeable state of the membrane allows for controlled changes in transmembrane electrical potentials. Once an impulse is generated by the pacemaking cells of the sinoatrial node (SA node), the primary site of automaticity, and assuming no pathologies exist, the interior of the right and left atrial myocytes become positive as Ca^{2+} ions enter the cell, depolarizing the area. Depolarization causes simultaneous right and left atrial contraction due to the structure of the myocytes' myofibrils. Sodium ions (Na^{+}) conduct the wave of depolarization until encountering the atrioventricular node (AV node). Depolarization continues at a slower pace due to the activity of Ca^{2+} ions, permitting perfusion of the right and left ventricles from the atria. The depolarization then continues to areas of the ventricular conduction system, propagating at a more rapid pace through the movement of Na^{+} ions. Repolarization occurs, returning the polarized state of the myocytes, through the removal of K^{+} ions. The aforementioned reactions to ionic movement are also associated with mechanical action of the myocardium, all of which is documented on the ECG.[8]

Electrical properties of the skin and the electrode-skin interface

An electrode is a skin sensor that detects biological electrical activity. The electrode transduces bioelectrical current produced by the movement of ions into current carried by electrons, thus enabling the ECG to record the signal. Various interfaces exist within the electrode and between the electrode and tissue that permit the transduction of signals, of which, the electrolyte-electrode interface and the electrode-skin interface are of particular interest.[9] The chemical reaction, or ionic-electronic current transduction, occurs at the surface AgCl layer of the electrode. Concerning the wet electrode, transduction occurs at the AgCl layer of the electrode and is facilitated by the electrolytic gel surface layer. The current then flows through the conductive Ag metal and is propagated through the lead wires to the recording device.[10] Concerning the dry electrode, the pattern of current flow only deviates at the interface of the electrolytic gel and the electrode, as it is nonexistent in this electrode type due to the absence of gel. Because this device relays information that has tremendous clinical value, it is important that it reflect only cardiac signal, rather than signal noise from other sources. It is imperative to create an electrode-skin interface with both low electrical impedance and low susceptibility to motion artifact.[11]

In order to decrease electrical impedance, or resistance, at the location of the electrode-skin interface, a basic understanding of bioelectrical properties of the skin is essential. The skin has three main layers: the epidermis, dermis, and hypodermis, or subcutaneous tissue. The outermost layer of the epidermis, the most superficial layer, is the stratum corneum (SC). The SC is considered an area of increased electrical impedance as it is a fluid barrier that is composed of dead cells approaching discharge.[12] The dermis, which lies beneath the epidermis, is considered a more viable layer as it has a rich vascular supply, among other characteristics. This area is considered to have high electrical conductivity, comparable to an electrolyte.[13] It would therefore be opportune to circumvent the SC in favor of the deeper regions when establishing the electrode-skin interface.[14] This is typically achieved with proper skin preparation, which entails the removal of the dead cells through abrasion in order to reduce electrical impedance and improve electrical conductivity; however, bypassing this area, in lieu of removal, would also be sufficient.[12,15]

Statement of Problem

Standard gel electrodes, specifically the Ag/ AgCl wet electrodes, are commonly used in clinical and research settings. These electrodes rely on an electrolytic gel to facilitate signal transduction. The reliance on the “wet” component of this electrode poses numerous disadvantages, some of which include: aggressive skin preparation, skin irritation, electrolyte gel dehydration, and electrode expiration. An objective in electrode development is the construction of an electrode that causes the least amount of aggravation for the patient, and the least amount of problems for the clinician. Sources of irritation for the patient may include lengthy skin preparation, skin preparation discomfort, and electrolyte gel or electrode tape irritation. Problems for the clinician may include increased cost of electrode replacement, decreased patient compliance, and difficulty with interpretation. [11,16] Many of the aforementioned issues arise due to inaccurate signal display, due to artifact and noise; therefore, the accuracy of the ECG signal is of the utmost importance when investigating the success of a particular device.

Orbital Research Incorporated (ORI, Cleveland, OH) has developed a dry electrode that may circumvent many of the potential disadvantages of the wet electrode. This device does not rely on an electrolytic gel to aid in signal transduction and therefore may avoid issues of electrode expiration and skin irritation. Orbital has satisfied many of the general recommendations for the development of new sensors in the construction of this device, such as using non-intrusive methods and using a more agreeable skin preparation approach.[17] The ORI electrode was designed with micro-features at the electrode-skin interface which gently infiltrate the SC layer of the skin, accessing deeper regions, therefore establishing a frictional mechanical electrode-skin interface (Appendix A). The infiltration occurs through the depression of the micro-features on the skin, which in addition to creating a mechanical interface, also may reduce motion artifact as it increases proximity to more electrically conductive tissues. The translucent adhesive component of the electrode permits continuous skin observation. In previous research it was established that over a continuous period of 48 hours the original ORI dry electrode, which was constructed with more aggressive micro-penetrators (Appendix B), produced a comparable signal quality to the 3M™ Red Dot™ 2560 wet electrode (Appendix C), without the electrolytic solution and aggressive skin preparation.[18]

Research Question

Specific Aim 1: Is there a significant difference in the ECG signal quality between the two different types of electrodes over an extended duration of continuous wear (96 hours) when subjected to equivalent testing conditions: the standard gel electrode, 3M™ Red Dot™ 2560 electrode (3M, St. Paul, MN) and the Orbital Research Incorporated dry electrode (ORI, Cleveland, OH)?

Specific Aim 2: Is there a significant difference in the ECG signal quality in the wet electrode over an extended duration of continuous wear (96 hours); meaning does significant signal deterioration exist over time?

Specific Aim 3: Is there a significant difference in the ECG signal quality in the dry electrode over an extended duration of continuous wear (96 hours); meaning does significant signal deterioration exist over time?

Purpose of the Study

The investigation of the signal quality of two different types of disposable electrodes, wet (3M, St. Paul, MN) and dry (ORI, Cleveland, OH) is necessary from both a research and clinical perspective. The purpose of this study was to investigate if differences in signal quality existed between two different electrode types over a 96 hour period of continuous wear. Of particular interest were the differences in signal quality that were reflected by the deterioration of the signal, quantified using the concept of signal-to-noise ratio (SNR). A decreased SNR is indicative of signal deterioration. SNR assessments were made both within the electrode types, comparing the potential deterioration within the electrode throughout the length of wear, and also between the two electrode types, comparing the potential deterioration between the wet and dry electrodes throughout the length of wear. The term “wet electrode” is used synonymously in this investigation with the standard gel 3M™ Red Dot™ 2560 electrode (3M, St. Paul, MN). The term “dry electrode” is used synonymously in this investigation with the ORI dry electrode ORI, Cleveland, OH). Deterioration was assessed while considering both the time elapsed (0, 24, 48, 72, and 96 hours), as well as the stage of data collection (Supine, Standing, 1.7 mph/0%, 1.7 mph/10%, 2.5 mph/12%, Recovery).

Hypotheses

Hypothesis 1: There will not be a significant difference in the ECG signal quality between the two different electrode types when worn continuously for an extended duration (96 hours) and subjected to the same testing conditions.

Hypothesis 2: There will not be a significant difference in the ECG signal quality in the wet electrode when worn continuously for an extended duration (96 hours); meaning significant deterioration of signal quality will not occur.

Hypothesis 3: There will not be a significant difference in the ECG signal quality in the dry electrode when worn continuously for an extended duration (96 hours); meaning significant deterioration of signal quality will not occur.

Definition of Terms

Several frequently used terms have been defined below:

Biopotential Signal: The movement of ions across a biological membrane that provides information regarding physiologic electrical activity. The biopotential signal is detected by the electrode and reflects the physiologic movement of ions within the myocardium that causes the muscle's contraction and relaxation.[13]

ECG Signal: The movement of electrons, the current in metals, transduced from ions, the current in tissue, measured in voltage.[6]

Electrocardiogram (ECG): A recording of the endogenic electrical activity of the myocardium.[6]

Electrode: A skin sensor that detects biological electrical activity; transduces bioelectrical signals produced by the movement of ions into electrical voltage, thus enabling the electrocardiogram to record the signal.[10]

Electrolyte: A substance that can dissociate into ions and is thus capable of conducting an electrical signal.[19]

Ion: An electrically charged particle; anion, cation.[19] The endogenic electrical activity of the myocardium is directed by ionic conductance.[8]

Noise: A component to the signal measured that originated from a source other than the source of interest.[20] In the context of this investigation, noise would originate from anything that was not cardiac signal.

Polarity: The distinction between a cell's negative and positive charge due to the distribution of ions.[19] Polarity in the context of this investigation concerns the membrane's interior and exterior charged state. A myocyte is in a polarized state when a negatively charged interior is paired with a positively charged exterior. A myocyte is in a nonpolarized state when a positively charged interior is paired with a positively charged exterior.[8]

Signal-to-Noise Ratio (SNR): The ratio of the signal power to the noise power; a reflection of the purity of the signal.[21]

Stratum Corneum (SC): The outermost layer of the epidermis, the most superficial layer of the skin, which is composed of dead and dry cells that are approaching detachment. This is an area of low electrical activity that must be avoided in order to reduce electrical impedance.[14]

CHAPTER II

LITERATURE REVIEW

Electrodes

Two different types of electrodes were tested in this study. Wet electrodes are so named because of the wet electrolytic solution or gel included in the electrode, which creates both an electrolyte-electrode interface and an electrolyte-skin interface. Dry electrodes are so named because of the absence of the electrolytic solutions or gels to the electrode. When discussing these electrodes it is appropriate to discuss the electrode-skin interface.[22]

The ORI dry electrode is an Ag/AgCl coated polymer and the 3M™ Red Dot™ 2560 electrode consists of an Ag base structure with an AgCl coated surface.[22] The Red Dot also contains an electrolytic gel at the AgCl surface to aid in conduction. Choosing non-polarized electrodes, such as both electrode types utilized in this investigation, are more appropriate as polarizable electrodes have various limitations in the presence of motion and various limitations if the measurement involves a low frequency signal, both of which are involved in ECGs.[22]

Wet Electrodes versus Dry Electrodes

Although the most commonly used wet electrode is the Ag/AgCl type, there are various disadvantages to its use. Signal quality may deteriorate during long-term use as the electrolytic gel, the wet component, dehydrates. [3,11,12,17,23] The potential for electrolytic gel dehydration implies also that the wet electrode has an expiration date associated with its production. Skin irritation due to abrasion or electrolytic solution may result as well. In addition to the aforementioned disadvantages, the extent of skin preparation may pose a time consuming inconvenience for the physician or researcher. Time is required for the application of the electrolytic gel as well as for stabilization wait. Stabilization wait concerns the time spent to ensure sufficient diffusion of the electrolytic gel into the skin.[12] One objective in the field of biopotential signal measurement is the construction of a dry electrode, which would permit extended duration observation without time-consuming skin preparation and potential irritation associated with wet electrodes.[14] Although various advantages exist concerning dry electrode implementation, it has been demonstrated that a heightened potential for motion artifact exists with dry electrodes due to the lack of an electrolytic layer, increasing electrode-skin impedance. [23,24]

Searle and Kirkup[24] compared three types of electrodes, wet, dry, and insulating, in a small sample (n=5). Of importance to the current investigation was the comparison between the wet and dry electrode types. In the context of their investigation, “wet” referred to Ag/AgCl electrodes that utilize an electrolytic gel to establish a conductive path at the electrode-skin interface. This is in accordance with the wet electrode utilized in the current investigation. Also in the context of their investigation, “dry” referred to a benign metal used with no electrolyte at the electrode-skin interface. This differs from the dry electrode utilized in the current investigation which utilized an Ag/AgCl coated conductive polymer with micro-features. However, both electrodes are considered “dry” as an electrolytic gel is absent. All measurements were collected simultaneously in order to control for different environmental influences.[24]

In order to determine the effect of motion, an oscillating mechanical device was utilized for 15 minutes. The same machine was used for both electrode types to ensure that equal electrode movement was applied. The amount of artifact associated with the wet electrode varied little over the course of 15 minutes. In comparison, however, the dry electrode elicited greater artifact than the wet electrode initially, but lower artifact than the wet electrode at the completion of the testing segment. The authors suggested that this occurred due to the accumulation of perspiration. Not only does perspiration under the electrode hydrate the dry SC layer of the skin and provide it with an electrolytic solution, but it also increases electrode-skin adherence.[24] The improved adherence will reduce movement at the skin-electrode surface. These factors would contribute to the apparent decreased artifact over the length of wear. This consequence, increased dry electrode performance after a stabilization period, has also been demonstrated elsewhere.[22]

Liao and colleagues[16] investigated the performance of a novel dry sensor for electroencephalography (EEG) measurements. The novel dry sensor was manufactured with 17 spring contact probes, all of which were flexible, thus allowing tight contact with the scalp’s surface. The dry sensors’ signals were compared to those of a standard wet electrode. Prior to applying each type of electrode, skin preparations were made only for the standard wet electrode sites. The probes proved to provide stable EEG signals, demonstrating equivalent impedance measurements to those of the wet electrodes. Impedance values on hairy sites were actually lower for the dry sensor when compared to the wet electrode. Additionally, long term impedance measurements, conducted over three hours, were lower in the dry sensors compared to the wet electrode.[16]

Another investigation conducted by Wang and colleagues[25] concerned the performance of a novel dry electrode with micro-needles. Based on the skin's layered structure, the electrode was manufactured with micro-needles that were greater than 50 µm, but less than 100µm. A length within this range allowed penetration of the SC layer of skin, without disruption of the dermis and its associated pain response. The micro-needle silicon-based dry electrode's impedance and ability to extract EEG signals was assessed alongside a commercial wet electrode. The dry electrode resulted in lower impedances than the commercial electrode, despite the absence of skin preparation and electrolytic gel application. The EEG recordings, which were obtained simultaneously, were similar. It was determined that the novel dry electrode provided results that were comparable to the commercial electrode.[25]

Griss and colleagues[13] designed a dry electrode with spikes. The structure of the skin was a major consideration in the construction of the spikes, dictating the depth at which the spikes protruded. The spikes were coated with Ag/AgCl and were intended to circumvent the high impedance of the SC through perforation. The spiked dry electrodes reduced electrical impedance and application times when compared to the conventional wet electrodes. Despite the positive findings, it was also noted that approximately five percent of all electrodes utilized were returned with fractured spikes after removal.[13]

Taheri and colleagues[23] conducted an investigation concerning the design, fabrication, and assessment of a dry electrode for EEG recordings. The dry electrode consisted of a 3 mm stainless steel disk with a thick nitride coating mounted to a copper plate. The disk was then secured to the scalp through the use of a Velcro strap and attached to an impedance converting amplifier. The dry electrode was compared to the conventional wet electrode in three areas related to EEG recordings: spontaneous EEG, sensory evoked potentials, and cognitive evoked potentials. No significant differences were discovered in any of the three comparisons, thus suggesting that the performance of the dry electrode was comparable to the conventional wet electrode.[23]

Orbital Research Inc. has conducted various studies[18, 26] concerning a predecessor of the dry electrode utilized in this study. The first dry electrode was developed to circumvent the disadvantages of the conventional wet electrode through the removal of the electrolytic gel and SC abrasion. The difference between the predecessor and the ORI dry electrode used in the current study concerns its construction. The predecessor had a higher concentration of micro-features on the electrode surface, which were considered micro-penetrators as they were more aggressively designed.

ORI conducted two clinical studies[18, 26] to assess the dry electrode’s signal quality. The first[18] was conducted over a 48-hour testing period utilizing the Bruce exercise testing protocol. Eleven subjects (n=11) participated in the study, wearing a pair of the dry electrodes or a pair of conventional wet electrodes for two days, completing the testing protocol on each day. Following the two days of data collection, after removal of the previous pair, the other pair of electrodes was placed in the same position and testing was repeated. The testing protocol was conducted without any skin preparation prior to application. Data was processed utilizing Matlab™ and 6th order Daubechies wavelet technology. There were no statistically significant differences in signal quality between the two electrode types. The ECG strips acquired during the testing protocol were also analyzed to assess practical utility. A trained professional assessed each strip according to the American Heart Association "ECG Analysis Questions." It was concluded that the traces from both electrode types were acceptable.[18,26]

A second study concerning a comparison between the ORI dry electrode and the Medi-Trace 530 electrode, a wet electrode, was also conducted. Eighteen subjects (n=18) completed a testing protocol, which consisted of six stages: resting in the supine and standing position, the first three stages of the Bruce protocol, and a recovery stage. The six-stage protocol is identical to that utilized in this study. The wavelet analysis technique was similarly applied to the data collected, as well as a "peak to peak" analysis. Cardiologists performed qualitative assessments of the ECG traces. Again, no statistically significant differences existed between the two electrodes in regard to signal quality or clinical utility. Overall, it was illustrated that the ORI dry electrode, the predecessor to the dry electrode utilized in this study, could be viewed as an alternative to the conventional wet electrode concerning ECG applications.[26]

Electrical Noise

In the assessment of an ECG a natural assumption is that the output is an accurate representation of the input, the myocardial endogenic behavior; however, the signal may be impure due to inference and the superimposition of contaminating signals from other sources, also recognized as artifact or electrical noise.[20] It is imperative to consider the source of electrical noise in order to postulate potential means of circumventing or reducing said artifact.

Huigen and colleagues[27] investigated the source of electrical noise in surface electrodes, primarily focusing on the metal-electrolyte interface and the electrolyte-skin interface. Two main electrode types were utilized in the investigation, wet gel electrodes (3M Red Dot 2255 Ag Ag/Cl) and hydrogel electrodes (3MRed Dot 2330 Ag Ag/Cl and Blue Sensor BS3500 tin). Skin preparation was consistent among the electrodes, entailing sandpaper-assisted skin abrasion and alcohol cleaning on the inner forearm. All measurements were carried out following electrode application, and the time between measurements utilizing different electrodes was at least two days. Huigen and colleagues[27] discovered that the noise from the metal-electrolyte interface, which was investigated by placing two electrodes face-to-face, thus excluding the electrolyte-skin interface altogether, was negligible. Low impedance values associated with the metal-electrolyte interface contributed to this assertion. It was discovered that the electrolyte-skin interface contributed the most noise, and furthermore, that the hydrogel-containing electrodes contributed higher noise than the wet gel electrodes. The hydrogel electrodes were also associated with higher impedance values. The authors suggested that this could be attributed to the ability of the wet gel to saturate the upper layer of skin, which was illustrated by the decreased noise noted. The hydrogel electrodes lacked this ability because they are considered hydrophilic and therefore have the potential to dehydrate the skin, increasing its reliance on sweat gland behavior. The authors thus concluded that the origin of the noise in surface electrodes was dependent on the electrode's gel type and the properties of the subject's skin.[27]

As previously stated, the signal quality of electrodes that rely on an electrolytic gel, wet electrodes, may deteriorate as the wet component dehydrates.3[,11,12,17,23] In a study conducted by Wiese and colleagues[3], electrodes were purposely degraded and artificially aged by exposing them for four days to air. As wet electrodes dehydrate, electrical impedance values increase, increasing the electrode's susceptibility to motion artifact. Increased artifact increases the likelihood of inaccurate signal recordings. The objective of the study was to establish a predictable level of impedance at which a significant increase in missed QRS complexes results. This finding would indicate when electrodes require replacement and therefore would also decrease the likelihood of inaccurate ECG recordings. Twelve subjects (n=12) were utilized in the protocol, each performing the same simple movements while wearing different electrodes. The investigators quantified both the missed QRS complexes and any extra complexes. It was found that impedance was greater concerning the electrodes that were degraded, as anticipated. Although there was a correlation between increased impedance and increased ECG error, it was determined that impedance was not a predictive means for assessing degraded electrodes. The correlation was not linear, and therefore, unable to clearly indicate a threshold level that would result in significantly more error.3

Electrode placement should be taken into consideration, choosing anatomical sites that minimize the potential electromyographic (EMG) input and motion artifact due to excessive skin motion.[27] Electrical noise proves to be the most influential during assessments that involve ambulatory conditions, such as cardiac stress tests.[28] In order to decrease motion artifact it is important to avoid skin stretch. In order to avoid skin stretch, which results in changes in dermal electrical potential and thus is depicted as motion artifact, the SC layer of the skin must be disturbed. Disturbance can occur through abrasion, the addition of an electrolytic gel, or through the penetration or indentation of the SC layer. Although abrasion is a commonly used method as it reduces changes in electrical potential to a negligible amount, the removal of the SC increases the likelihood of dermal irritation, especially with the addition of an electrolytic solution.[20]

Tam and Webster[28] investigated the effect of skin abrasion on motion artifact in ECG recordings. It was discovered that regardless of the source of motion artifact, the most significant decrease in skin potential and consequently the most significant decrease in motion artifact occurred following abrasion of the skin. Another finding concerned the use of electrolytic gels over time (i.e. seven days). A variety of gels were utilized, each of which was removed daily and then reapplied to the skin. Gel application occurred both on abraded and undisturbed skin. Although overall redness and itchiness was noted, it was discovered that more severe reactions to the gel occurred at the sites of the abraded skin. The deeper the abrasion was made, the sooner the discomfort was apparent. The authors concluded that skin abrasion reduces motion artifact, but the abrasion may increase susceptibility to irritation with more concentrated solutions. This reaction was of course related to the degree of abrasion.[28]

Talhouet and Webster[15] determined that impedance decreased with increased skin abrasion, which is in accordance with the results of a previous study.[28] The relationship between artifact and electrical impedance was investigated in 10 subjects (n=10) through the successive stripping of the skin using Scotch Tape. Between each bout of skin stripping, artifact and impedance was measured. These factors were evaluated in response to the stretching of the skin. For all subjects, the greatest decrease in impedance resulted between the second and fourth stripping. Impedance was at its minimum by the12th round of skin stripping for most subjects, although others required less. This was dependent on the skin's initial impedance level. The study reinforced the notion that skin potential and electrical impedance are dependent on the state of the skin. Through the removal of the SC, artifact and skin potential appear to decrease, thus providing a less noisy signal.[15]

A puncture technique has also been suggested by Burbank and Webster[29], involving a blood lancet that protrudes 0.5 mm and pierces the skin 20 times. The results of their investigation were promising when assessing non-punctured versus punctured ECG signals, particularity while running on the treadmill. Through their investigation, the major cause of motion artifact, skin stretch, was reduced through the disruption of the SC.[29] The puncture technique, however, may not be as easily accepted by subjects. This thought led ORI to construct a different dry electrode, one which does not have micro-penetrators, as the first had, but has less aggressive micro-features instead.

The electrode itself should also be considered as a source of motion artifact; however, coating the silver with AgCl reduces this artifact, which is in accordance with both the wet and dry electrodes of interest in the current investigation. Not to be disregarded, power line interference, static electricity and radio-frequency are other sources of noise that must be addressed. The removal of those components is somewhat more intensive and requires technologically dependent means, such as filters and amplifiers.[20]

Signal Analysis Wavelet Transform (SNR)

A mathematical transformation allows the differentiation between signal and noise. In the evaluation of ECGs it is important to have an accurate description of the waves according to their frequency and location in time, thus time-frequency representation of the signal is essential. A Fourier transform, therefore, is not an ideal approach as it is unable to provide a time component. The wavelet transform, a time-frequency transform, is of particular interest. The wavelet transform consists of a set of analyzing wavelets, which allows ECG signal deconstruction.2 The appropriate wavelet transform selection is dependent on its application and the morphology of the signal of interest.[30] The Daubechies family of wavelets may be the most appropriate in ECG signal processing as they have the capacity to recognize minute detail overlooked by other algorithms; they resemble the QRS complex, and they operate in a low frequency spectrum, similar to the ECG.2[,30] In a study conducted by Mahmoodabadi and colleagues[30], the Daubechies 6 (db6) wavelet transform and the Daubechies 4 (db4) wavelet transform were utilized for comparison. The authors concluded that the ECG feature extraction was superior while using db6, compared to db4.[30]

CHAPTER III

METHODS

Overview

The current experimental investigation concerned potential differences in the deterioration of ECG signal quality between two different types of electrodes over an extended duration (96 hours): the Orbital Research Incorporated (ORI) dry electrode (ORI, Cleveland, OH) and a standard gel electrode, 3M™ Red Dot™ 2560 electrode (3M, St. Paul, MN). The study involved monitoring the independent variable, the type of electrode, and assessing the dependent variable, signal quality, calculated as the signal-to-noise (SNR) ratio. Also included in the investigation was the documentation of subjective information. The extent of the subjective information gathered included anecdotal information concerning electrode-induced pain or annoyance as well as any visible electrode site irritation or other issues concerning the electrodes noted by the investigator. This experimental research was conducted over a 96 hour period, where the subjects acted as their own controls, wearing both electrodes in the same configuration simultaneously. The study was approved by the Institutional Review Board (IRB) of Cleveland State University, Cleveland, Ohio.

Subjects

A convenience sample of volunteers from Cleveland State University and the surrounding Cleveland community was utilized. Twenty healthy adult volunteer subjects (M 25.1 ± 4.3 years, F 26.2 ± 6.4 years), gender being equally represented (10 males, 10 females), were recruited by means of a recruitment flier (Appendix D), or through verbal invitation. Study procedures, benefits, and risks were explained verbally and provided in the informed consent (Appendix E). Informed consent was obtained from each subject prior to any additional study procedures. Confidentiality was maintained for all subjects, with names and personal information stored in a locked file in the Human Performance Laboratory at CSU accessible only to the investigators. Any publication of data will only use group data and not identify subjects by name.

Procedures

Immediately after obtaining informed consent from each subject, he or she was directed into a private room for electrode placement. In order to establish a consistent baseline, skin preparation was the same at both sites prior to electrode adhesion. Skin preparation occurred only on day zero (0) of the experimental period, and entailed the following: cleaning with an alcohol swab, drying the area after cleaning, and the administration and removal of Nuprep (Weaver and Company, Aurora, CO), an electrical impedance-lowering gel. Each set of electrodes, the standard 3M™ Red Dot™ 2560 gel electrode and the ORI dry electrode, were placed in a Lead II configuration (Right arm (RA), Left leg (LL)) (Figure 2). Subject electrode lead placement, A or B, was determined through randomization. Electrodes were placed directly adjacent to one another.

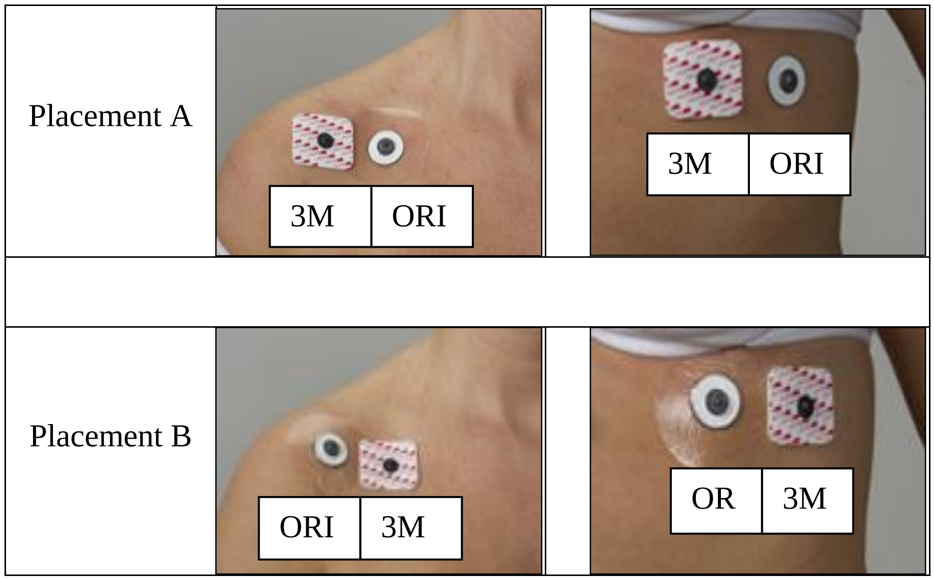

Figure 2: Electrode Placement

Subjects were instructed to leave the electrodes in place throughout the entire experimental period. In the event of intolerable discomfort, subjects were instructed to remove such electrode(s) at their discretion; however, it was explained that this would terminate any further participation in the study. Subjects were provided additional adhesive to place over, not replace, the original adhesive if electrodes demonstrated even the slightest sign that they may become detached. Subjects were instructed to maintain typical behaviors, including bathing, over the course of the 96 hour experimental period, with the exception of full submersion in water.

On day zero (0), immediately after secure electrode placement, a standard ECG telemetry unit (ScottCare TeleRehab System, Cleveland, OH) was utilized for all data collection (day 0-4). Simultaneous tracings were collected on two separate channels, each assigned to a specific electrode pair continuously at 120Hz throughout each testing session. In an attempt to ensure that signal quality was not affected by the telemetry's recording channel, the channels were alternated each day. Each subject's ECG was collected throughout the six, three minute stages, totaling 18 minutes each day (day 0, 1, 2, 3, 4). The six stages included two bouts of rest, supine and standing, followed by three submaximal exercise stages on a motor driven treadmill, ending with one additional stage of rest (recovery) in the standing position (Table 1).

Table 1: Daily Data Collection Protocol

Stage	Position	Time (minutes)	Running Time
1	Supine	3	0-3
2	Standing	3	3-6
3	1.7 mph/0%	3	6-9
4	1.7 mph/ 10%	3	9-12
5	2.5 mph/ 12%	3	12-15
6	Recovery	3	15-18

The test was terminated when either the protocol (18 minute duration) was complete, or if the subject reached an exercise intensity greater than 85% of his or her age-predicted maximum heart rate (HR_{max}), defined as 220-age.[31] The former was the cause of termination for all subjects.

Signal Analysis

Data collected using the telemetry unit was de-noised, removing unwanted electrical signals that increased the difficulty of the detection of the signal of interest (ECG), by Matlab™ R2010b software (The MathWorks Inc., Natick, MA). The signal extracted from the telemetry unit was in its raw form, meaning it was in an unprocessed state and included substantial electrical noise from other non-cardiac sources, which increased the difficulty of making any reasonable comparisons of signal strength between the electrodes. In this state both slow and fast noise was evident; therefore, the signal's decomposition through filtering was of value. The slow noise, which could have arisen due to inadequate skin-electrode interface or other artifact, was removed first by isolating baseline wander, therefore preventing the isoelectric line from establishing a new baseline.

Once the slow noise was removed, the fast noise was filtered out through a series of steps as the contamination would have also increased the difficulty of determining signal strength. In brief, the two main constituents of fast noise are: line interference from other sources of electricity (60 Hz) and white noise. Line interference, or electromagnetic interference, results from the electrical current passing through the wires of other power sources in near proximity to the subject.[23] This interference is generally considered 60 Hz in the United States (US), as that figure is considered the power that is used daily in the US. Matlab first filtered out the 60 Hz source of noise, by isolating the noise, while keeping remaining signals. Upon its successful removal, the removal of white noise was necessary. Unfortunately, due to the complexity of white noise, or thermal noise, the utilization of a transform was imperative. A transform, or mathematical transformation, is applied to a signal. The appropriate transform is dependent on the signal. The signal of interest, the ECG, is considered a non-stationary signal, meaning that the frequency of the signal differs at different time points. Similar to numerous other biological signals, a wavelet transform is appropriate as it has the ability to provide both time and frequency data simultaneously.[32] The Daubechies wavelet family resembles an ECG most closely;

therefore, it was advantageous to choose a wavelet transform from amongst that group. Sixth order Daubechies (db6) wavelet transform (WT) technology was used by Matlab to remove the white noise. The WT was superimposed on the signal, isolating particular features, and removing those that were not identified as cardiac signal.[30] The remaining signal was considered a clean and processed signal, or the best estimate of one. The processed signal was considered the endogenic signal by the myocardium, without any of the noise.

Once the signal was processed, the signal-to-noise ratio (SNR) for each subject, at each stage, each day, was calculated. Essentially, the SNR is the ratio of signal power, the signal of interest, to noise power, undesirable signal, expressed as decibels.[21] The SNR was defined in Matlab as follows:[18]

$$SNR = 10 \cdot \log\left(\frac{\sigma^2(Signal)}{\sigma^2(Noise)}\right) = 10 \cdot \log\left(\frac{\mathrm{var}(Signal)}{\mathrm{var}(Noise)}\right) \quad (dB)$$

The signal component of the equation was the processed signal described above. The noise component of the equation was the fast noise, not the summation of the slow and fast, as the fast component was the more difficult of the two to remove. The signal-to-noise ratio (SNR) provided a quantitative measure for statistical comparison. A higher SNR is indicative of more signal and less noise, which is desired.

Data Analysis

The raw data collected on the telemetry unit was transported to another computer equipped with Matlab™ for SNR calculation. The SNR was calculated from the last 2.5

minutes of each 3 minute stage, avoiding any interference the period of transition may have caused. The electrode type used, subject, day, and stage of testing were noted during calculation. From this raw data, mean SNRs of each type of electrode, wet and dry, were calculated for each stage of testing on each day.

Analyses were conducted concerning both within electrode type and between electrode types. Repeated measures ANOVAs were utilized to assess for any deterioration in the ECG signal quality of the wet and dry electrode at all stages (Supine, Standing, 1.7 mph/0%, 1.7 mph/10%, 2.5 mph/12%, Recovery) over the experimental period (days 0-4). If significant differences were found, paired *t* tests were used to identify the specific paired comparisons which differed. Additionally, a repeated measures ANOVA was utilized to assess the interaction of the electrode type (wet or dry) and time (day 0-4). Similarly, paired *t* tests were used to identify specific sources of significant difference. Statistical analyses were carried out using PASW (SPSS, version 18.0). Significance was accepted at $p < .05$ concerning the repeated measures ANOVAs. In order to reduce Type I error, a protected *t* test was utilized in order to determine the appropriate p value. The probability value (.05) was adjusted for the number of comparisons (.05/5); therefore, significance was accepted at $p < .01$ concerning the paired *t* tests.

CHAPTER IV

RESULTS AND DISCUSSION OF DATA

RESULTS

The purpose of the current investigation was to determine differences in signal quality between the dry electrode (ORI, Cleveland, OH) and the standard gel electrode, 3M™ Red Dot™ 2560 electrode (3M, St. Paul, MN), over a 96 hour period of continuous wear. The aforementioned objective was assessed specifically through the consideration of three particular inquiries, concerning between and within comparisons. Thus, the majority of the results section concerned the following sections: comparison of ECG signal quality between the wet and dry electrodes over an extended duration of continuous wear, assessment of ECG signal quality in the wet electrode over an extended duration of continuous wear, and assessment of ECG signal quality in the dry electrode over an extended duration of continuous wear. Reflective of the outcome measure of interest, signal quality, SNRs were calculated for each subject, each day, at each stage to be used in the data analysis. A higher SNR is indicative of better signal quality and less noise, which is preferred. Subjective data was also noted. Discussion and interpretation of data follows.

Physical Characteristics

Twenty healthy adult volunteer subjects participated in the research study, gender being equally represented (10 males, 10 females). All subjects completed the research protocol in its entirety, each subject acting as his or her own control wearing both electrode types simultaneously and continuously for 96 hours in a lead II configuration. The physical characteristics of the subjects are presented in Table 2.

Table 2: Physical Characteristics of the Subjects (mean ± SD)

	Age (year)	Height (cm)	Weight (kg)
Females (n=10)	26.2 ± 6.37	169.0 ± 7.9	69.9± 19.9
Males (n=10)	25.1 ± 4.28	181.0 ± 6.2	79.9 ± 5.3

SD: Standard deviation

Comparison of ECG Signal Quality between the Wet and Dry Electrodes Over an Extended Duration of Continuous Wear

A repeated measures ANOVA was utilized to assess the interaction of the electrode type (wet and dry) and time (day 0-4). Table 3 illustrates the interaction of time (day 0-4) and electrode type (wet versus dry).

Table 3: SNR: Wet versus Dry Comparison on Successive Days

Wet versus Dry (n=40)				
Interaction of Time and Electrode				
Stage	Day/ Electrode	Mean SNR	SD	p
Supine	0/ Wet	19.34	±2.57	
	0/ Dry	19.89	±2.06	
	1/ Wet	19.96	±2.00	
	1/ Dry	19.33	±1.72	
	2/ Wet	19.95	±2.11	
	2/ Dry	18.73	±1.97	
	3/ Wet	20.05	±1.74	
	3/ Dry	18.80	±2.15	
	4/ Wet	20.16	±2.16	
	4/ Dry	18.96	±2.01	
				*0.014
Standing	0/ Wet	17.83	±2.62	
	0/ Dry	18.65	±2.46	
	1/ Wet	18.68	±2.35	
	1/ Dry	18.16	±2.16	
	2/ Wet	18.64	±2.29	
	2/ Dry	17.79	±2.48	
	3/ Wet	18.82	±2.24	
	3/ Dry	18.86	±2.61	
	4/ Wet	18.80	±2.27	
	4/ Dry	17.85	±2.22	
				0.076
1.7 mph/0%	0/ Wet	18.83	±2.34	
	0/ Dry	19.91	±2.15	
	1/ Wet	19.01	±2.34	
	1/ Dry	20.33	±2.83	
	2/ Wet	19.47	±2.26	
	2/ Dry	19.78	±2.48	
	3/ Wet	19.50	±2.74	
	3/ Dry	20.94	±3.87	
	4/ Wet	19.22	±2.17	
	4/ Dry	19.89	±2.06	
				0.601

Table 3 (Continued)

Wet versus Dry (n=40) (continued)				
Interaction of Time and Electrode				
1.7 mph/ 10%	0/ Wet	18.88	±2.22	
	0/ Dry	19.52	±2.23	
	1/ Wet	18.43	±2.17	
	1/ Dry	20.09	±2.86	
	2/ Wet	18.52	±2.08	
	2/ Dry	19.27	±1.73	
	3/ Wet	18.87	±2.10	
	3/ Dry	20.23	±3.70	
	4/ Wet	18.99	±2.41	
	4/ Dry	19.70	±2.49	
				0.615
2.5 mph/ 12%	0/ Wet	19.62	±2.82	
	0/ Dry	20.29	±2.50	
	1/ Wet	18.43	±2.12	
	1/ Dry	19.64	±2.06	
	2/ Wet	18.26	±2.23	
	2/ Dry	18.67	±2.91	
	3/ Wet	18.74	±2.54	
	3/ Dry	19.9	±2.99	
	4/ Wet	18.91	±2.52	
	4/ Dry	19.77	±2.33	
				0.906
Recovery	0/ Wet	18.50	±3.13	
	0/ Dry	18.89	±2.49	
	1/ Wet	18.62	±2.45	
	1/ Dry	18.15	±2.21	
	2/ Wet	18.61	±2.30	
	2/ Dry	17.05	±2.73	
	3/ Wet	18.53	±2.32	
	3/ Dry	17.25	±2.86	
	4/ Wet	18.78	±2.45	
	4/ Dry	17.76	±2.92	
				0.206

*Significant ($p < .05$); SD: Standard deviation

No significant differences existed between the wet and dry electrodes over time during all non-supine stages ($p \geq 0.05$). However, there was a significant ($p = .014$) interaction of electrode type and time during the supine stage. Table 4 illustrates the location of the significant differences between the wet and dry electrodes over time in the supine position (paired *t* test).

Table 4: Wet versus Dry: Supine Stage

Wet versus Dry (n=40)			
Pair	Mean SNR	SD	(Sig. 2-tailed)
Day0Wet	19.34	±2.57	
Day0Dry	19.89	±2.06	0.255
Day1Wet	19.96	±2.00	
Day1Dry	19.33	±1.72	0.033
Day2Wet	19.94	±2.11	
Day2Dry	18.73	±1.97	*0.006
Day3Wet	20.05	±1.74	
Day3Dry	18.80	±2.15	0.017
Day4Wet	20.16	±2.16	
Day4Dry	18.96	±2.21	*0.008

*Significant ($p < .01$); SD: Standard deviation

The wet electrode had significantly ($P < .01$) greater SNRs than the dry electrode on days 2 and 4.

Assessment of ECG Signal Quality in the Wet Electrode over an Extended Duration of Continuous Wear

A repeated measures ANOVA was utilized to assess deterioration in the ECG signal quality of the wet electrode at all stages (Supine, Standing, 1.7 mph/0%, 1.7 mph/10%, 2.5 mph/12%, Recovery) over the experimental period (days 0-4). Table 5 illustrates wet electrode mean SNR values over 96 hours of wear at different stages. No significant differences were found, with the exception of the Standing stage (p .049).

In order to determine the location of the significant differences, a paired *t* test was conducted on the data associated with the Standing stage. Table 6 illustrates the location of the significant differences in the aforementioned stage over the experimental period.

Table 5: Wet Electrode SNR Data over Time

Wet Electrode: SNR Data over Time (n=20)				
Day	Stage	Mean SNR	SD	Sig.
0	Supine	19.34	±2.57	
1	Supine	19.96	±2.00	
2	Supine	19.95	±2.11	
3	Supine	20.05	±1.74	
4	Supine	20.16	±2.16	
				0.202
0	Standing	17.83	±2.62	
1	Standing	18.68	±2.35	
2	Standing	18.64	±2.29	
3	Standing	18.82	±2.24	
4	Standing	18.80	±2.27	
				*0.049
0	1.7 mph/0%	18.83	±2.34	
1	1.7 mph/0%	19.01	±2.34	
2	1.7 mph/0%	19.47	±2.26	
3	1.7 mph/0%	19.50	±2.74	
4	1.7 mph/0%	19.22	±2.17	
				0.489
0	1.7 mph/ 10%	18.88	±2.22	
1	1.7 mph/ 10%	18.43	±2.17	
2	1.7 mph/ 10%	18.52	±2.08	
3	1.7 mph/ 10%	18.87	±2.10	
4	1.7 mph/ 10%	18.97	±2.41	
				0.521
0	2.5 mph/ 12%	19.62	±2.82	
1	2.5 mph/ 12%	18.43	±2.12	
2	2.5 mph/ 12%	18.26	±2.23	
3	2.5 mph/ 12%	18.74	±2.54	
4	2.5 mph/ 12%	18.91	±2.52	
				0.179
0	Recovery	18.50	±3.13	
1	Recovery	18.62	±2.45	
2	Recovery	18.61	±2.30	
3	Recovery	18.53	±2.32	
4	Recovery	18.78	±2.45	
				0.934

*Significant ($p < .05$); SD: Standard deviation

Table 6: Wet Electrode: Standing Stage

Wet Electrode Standing Stage (n=20)				
Pair	Pre-standing	Mean SNR	SD	Sig. (2-tailed)
1	day0	17.83	±2.62	
	day1	18.68	±2.35	*0.007
2	day0	17.83	±2.62	
	day2	18.64	±2.29	0.044
3	day0	17.83	±2.62	
	day3	18.82	±2.24	0.018
4	day0	17.83	±2.62	
	day4	18.80	±2.27	0.054
5	day1	18.68	±2.35	
	day2	18.64	±2.29	0.899
6	day1	18.68	±2.35	
	day3	18.82	±2.24	0.686
7	day1	18.68	±2.35	
	day4	18.80	±2.27	0.744
8	day2	18.64	±2.29	
	day3	18.82	±2.24	0.638
9	day2	18.64	±2.29	
	day4	18.80	±2.27	0.513
10	day3	18.82	±2.24	
	day4	18.80	±2.27	0.966

*Significant (p< .01); SD: Standard deviation

Significant (p< .01) differences were observed between day 0 and day 1. The mean SNR on day 1was significantly better than the mean SNR on day 0 of the wet electrode in the Standing stage. This finding is indicative of an improvement, rather than a decline, in signal quality. Hence, the consideration of this significant difference is superfluous in regard to the hypothesis as it is not reflective of a significant deterioration over time, but rather, an improvement.

Assessment of ECG Signal Quality in the Dry Electrode over an Extended Duration of Continuous Wear

A repeated measures ANOVA was utilized to assess deterioration in the ECG signal quality of the dry electrode at all stages (Supine, Standing, 1.7 mph/0%, 1.7 mph/10%, 2.5 mph/12%, Recovery) over the experimental period (days 0-4). Table 7 illustrates dry electrode mean SNR values over 96 hours of wear at different stages.

Table 7: Dry Electrode SNR Data over Time

Dry Electrode: SNR Data over Time (n=20)				
Day	Stage	Mean SNR	SD	Sig.
0	Supine	19.89	±2.06	
1	Supine	19.33	±1.72	
2	Supine	18.73	±1.97	
3	Supine	18.80	±2.15	
4	Supine	18.96	±2.21	0.108
0	Standing	18.65	±2.46	
1	Standing	18.16	±2.16	
2	Standing	17.79	±2.48	
3	Standing	18.86	±2.61	
4	Standing	17.85	±2.22	0.258
0	1.7 mph/0%	19.91	±2.15	
1	1.7 mph/0%	20.33	±2.83	
2	1.7 mph/0%	19.78	±2.48	
3	1.7 mph/0%	20.94	±3.87	
4	1.7 mph/0%	19.89	±2.06	0.450
0	1.7 mph/ 10%	19.52	±2.23	
1	1.7 mph/ 10%	20.09	±2.86	
2	1.7 mph/ 10%	19.27	±1.73	
3	1.7 mph/ 10%	20.23	±3.70	
4	1.7 mph/ 10%	19.70	±2.49	0.664
0	2.5 mph/ 12%	20.29	±2.50	
1	2.5 mph/ 12%	19.64	±2.06	
2	2.5 mph/ 12%	18.67	±2.91	
3	2.5 mph/ 12%	19.90	±2.99	
4	2.5 mph/ 12%	19.77	±2.33	0.279
0	Recovery	18.89	±2.49	
1	Recovery	18.15	±2.21	
2	Recovery	17.05	±2.73	
3	Recovery	17.25	±2.86	
4	Recovery	17.76	±2.92	0.068

*Significant ($p < .05$); SD: Standard deviation

No significant differences were found, therefore, the dry electrode signal quality did not significantly deteriorate over the duration of the study.

Assessment of Subjective Data

Also included in the investigation was the documentation of subjective information. The extent of the subjective information gathered included anecdotal information concerning electrode-induced pain or annoyance obtained from the subjects as well as any visible electrode site irritation or other issues concerning the electrodes noted by the investigator. These subjective considerations were necessary as the effectiveness of any electrode is void if people are unwilling to use them due to discomfort. All information was gathered immediately after electrode removal from each subject (Appendix E).

Both electrode types yielded similar incidences of electrode-induced irritation in the form of "itchiness," 16 subjects reporting the aforementioned complaint associated with the dry electrode, and 13 subjects associated with the wet electrode. Redness at the electrode site was also similar between the electrodes, with the wet electrode resulting in slightly more redness. For all subjects, skin indentations, impressions in the skin due to the micro-features, appeared at both dry electrode sites (Figure 3). Bruising occurred at the site of the dry electrode micro-features for 13 subjects, compared to one at the site of the wet electrodes. The left leg (LL) dry electrode site displayed more bruising than the right arm (RA) dry electrode site. Overall, the main aftereffects of extended electrode use, "itchiness" and redness at removal site, impacted the subjects similarly and was not dependent on electrode type, and all effects were transient.

Figure 3: Dry Electrode Residual Skin indentations

DISCUSSION

<u>ECG Signal Quality between the Wet and Dry Electrodes Over an Extended Duration of Continuous Wear</u>

There was a significant difference between the wet and dry electrodes during one of the six stages, Supine. This significant difference favored the wet electrode as the mean wet electrode SNRs on day 2 and 4 were greater than those of the dry electrode. The first hypothesis, which stated that there would not be a significant difference in ECG signal quality between the two different electrode types when worn for an extended duration, was therefore rejected due to the presence of a statistically significant difference in the Supine stage. This difference could be due to differences in electrode-skin contact when in the Supine position, as discussed later.

In discussing statistically significant differences in mean SNRs it is first important to note that a distinction between statistical significance and practical significance may be necessary, meaning, the difference determined based on mean SNR data may be negligible in a clinical setting. Effect size (ES) was calculated as it is a measure utilized to estimate practical meaningfulness of an outcome. The ES was 0.7 in the comparison of wet versus dry during the supine stage, which suggests that a meaningful difference does exist between the two groups. Although the ES suggests that the statistical difference is most likely practically significant, a clinical evaluation remains necessary.

Orbital Research Incorporated (ORI) completed a previous dry electrode study that revealed non-significant differences between the SNRs of the dry electrode, slightly different in construction, and the standard wet electrode. The ECG strips acquired were additionally analyzed by trained professionals according to the American Heart Association's "ECG Analysis Questions." The professionals indicated that both types of electrodes provided adequate traces.[26] It may be reasonable to suggest that clinical significance supersedes statistical significance based on SNR; therefore, a more qualitative analysis of this study's acquired strips may be needed for further clarification of the utility of the dry electrodes (Figure 4).

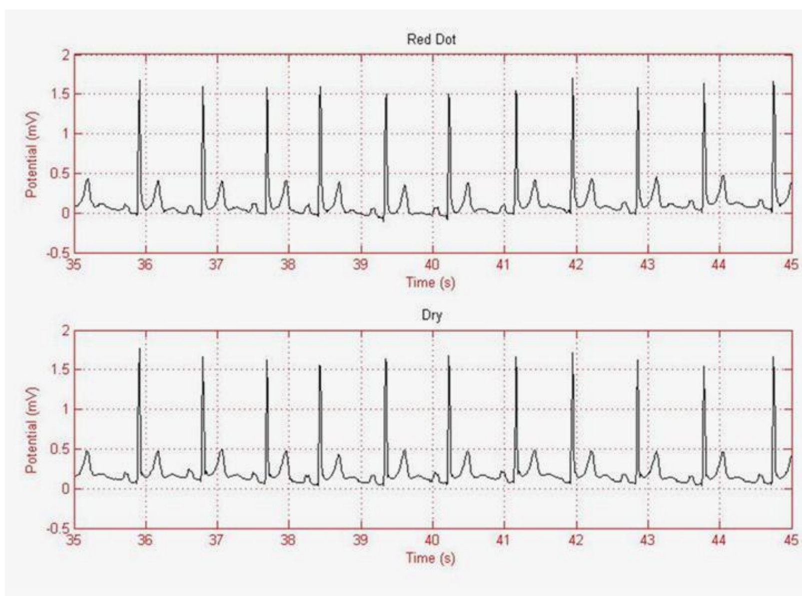

Figure 4: Two ECG Traces Acquired from Each Electrode Type at the Same Time Stamp
An example of what may be assessed qualitatively for clinical significance. Red dot: Wet electrode

One potential explanation for the observed difference between the wet and dry electrode during the Supine stage concerns the lack of perspiration. Any changes due to the activity of the sweat glands will affect electrical impedance and resistance.[23,24] This stage occurred each day prior to any potential sweat-inducing stages. However, this explanation did not hold true during the Standing stage as no difference was observed.

A previous study conducted by ORI concerning a dry electrode, from which the first hypothesis is grounded, utilized a similar dry electrode that had slightly different features. Statistically significant differences in SNR values between the standard gel electrode and the ORI dry electrode did not exist in the aforementioned study, indicating that the electrodes, which were worn for a shorter duration (48 hours continuously), were capable of producing similar signals at all stages of testing.[18] The features of the predecessor electrode, considered micro-penetrators, were sharper and thus potentially capable of greater SC disruption. The Supine stage may have been the most susceptible to the difference in construction. The sharper features of the dry electrodes used in the previous study may have allowed more disturbance of the SC, even during the Supine stage. The dry electrode of interest in this study may have experienced difficulty maintaining contact with the skin during the Supine stage as the pressure of the lead wires pulling downward was absent. Although this issue would have existed during the previous study, the sharper features may have established a mechanical interface more easily.

Because it is widely accepted that avoidance or removal of the SC layer of skin will reduce electrical impedance, it is suggested that the apparent difference between the results of the two studies most likely would be due to the difference in micro- structures and their effect on the SC.[15,28] Perhaps the predecessor achieved greater SC disruption, thus reducing impedance and motion artifact, and resulting in improved ECG recording quality.[15] In contrast to that explanation, another study utilized a dry electrode that had “probes” attached at the surface in the investigation of EEG signals. Similarly to the dry electrode of this study, the probes did not pierce the skin. The surface of the electrodes in the aforementioned study consisted of 17 “probes,” allowing 17 points of contact between the electrode and the scalp. Similar results to the conventional wet electrode were discovered, with the exception that the dry electrode produced a better signal on hairy sites.[16] The difference in micro- construction between the ORI dry electrode used in this investigation compared to the ORI dry electrode used in the previous investigation may or may not account for the difference observed in this study.

ECG Signal Quality in the Wet Electrode over an Extended Duration of Continuous Wear

A significant difference existed only in the Standing stage concerning the wet electrode over time, specifically between days 0 and 1. The mean SNR of days 1was significantly better than the mean SNR of day 0. Although there was a significant difference in ECG quality, it reflected an improvement, rather than deterioration, of signal quality. This observation was not anticipated, however, the second hypothesis, which stated that there would not be a significant difference in ECG signal quality in the wet electrode when worn continuously for an extended duration, was therefore accepted due to the absence of a statistically significant deterioration of signal quality.

Worth acknowledgement is the apparent reality that the wet electrode improved between the baseline (day 0) and day 1 of testing, reflected by an increased mean SNR. A possible explanation for the wet electrode’s improved signal between day 0 and day 1 concerns the activity of the electrolytic gel. The electrolytic gel may prove detrimental to the ECG's signal quality over an extended duration of wear due to the potential for dehydration.3,[11,12,17,23] In opposition to the aforementioned destructive effect, the electrolytic gel may improve signal quality under certain conditions. One purpose of the electrolytic gel is to saturate the dry SC layer of skin with electrolytes, which requires a stabilization period.[22,27,28] Without the proper allotment of time (five minutes has been used in a previous study) for the electrical potentials to stabilize, increased noise may result.[28] Therefore, the electrolytic gel may not perform properly immediately following its application. Concerning this investigation, upon electrode application, subjects were immediately engaged in the study protocol, not allowing a period of stabilization to occur. Compared to the supine stage, more motion artifact could have resulted from this stage. The improved signal quality apparent on day 1 when compared to day 0 may therefore be explained by inadequate electrolyte-skin stabilization on day 0 (baseline data).

ECG Signal Quality in the Dry Electrode over an Extended Duration of Continuous Wear

There was no significant difference over time within the dry electrode mean SNRs; therefore, the dry electrode signal quality did not significantly deteriorate over the study duration. The third hypothesis associated with this study, which stated that there would not be a significant difference in ECG signal quality in the dry electrode when worn continuously for an extended duration, was accepted. This result is similar to that of other ORI studies involving dry electrodes.[18]

Skin Irritations

As aforementioned, there were various transient irritations associated with both electrode types. Wet electrode-induced irritations were in accordance with previous findings; generalized itchiness and redness being the most common.[11,12,14,18,23] Dry electrode-induced irritations were similar; however, bruising occurred more frequently at the site of the dry electrode, when compared to the wet (n=13 to n=1, respectively). Bruising occurred most often at the dry electrode LL site, which may be correlated to the increased irritation reported at that site. The increased irritation may be related to the increased tendency of the subject to push downwards on the dry electrode in an attempt to relieve said “itchiness,” therefore, increasing the likelihood of bruising in this area.

For all subjects, skin indentations appeared at both dry electrode sites. This transient result discovered on the last day of the experimental period provides additional evidence that the dry electrode disturbed, but did not pierce, the SC layer of the skin. The micro-features were able to depress the skin’s upper layer, establishing a closer relationship with deeper and more electrically conductive tissues. The micro-features also increased friction at the electrode site, thus increasing the difficulty of lateral movement of the electrode. Because the micro-features on the surface of the dry electrode were not micro-penetrators, and therefore did not pierce through the SC, subject pain during application and removal was virtually nonexistent. Other studies concerning dry electrodes have been conducted involving micro-needles at the electrode’s surface, which pierce the skin, unlike the micro-features of the dry electrode utilized for this study.[12,13,25] Although the concept of their application is similar and the reduction of electrical impedance may be greater, the micro-needles may prove to be less conducive to patient/subject reception. In a study conducted by Griss and colleagues, a dry spiked electrode was designed and investigated. Despite the positive results concerning decreased impedance, it was discovered that approximately five percent of all electrodes applied revealed fractured spikes after removal, suggesting that the missing spikes were embedded in the affected subject's tissue.[13]

Adhesive issues were present for both electrode types. Over the experimental duration it was evident that the initial skin-electrode adhesion weakened over time. Concerning the dry electrode, the thin adhesive began to pull away from the skin over time, therefore, reducing the contact established between the electrode and the skin (Figure 3). The wet electrode shifted from its original position slightly. In some instances, both wet and dry electrodes were secured with additional tape. Between day 0 and day 3 this tape covered, but did not replace, the original electrode adhesive. In response to the apparent pulling away of the dry electrode adhesive, on day 4 the adhesive tape on the dry electrode was completely replaced for all subjects. utilizing the same electrode. However, no significant difference was found in signal quality in response to this change.

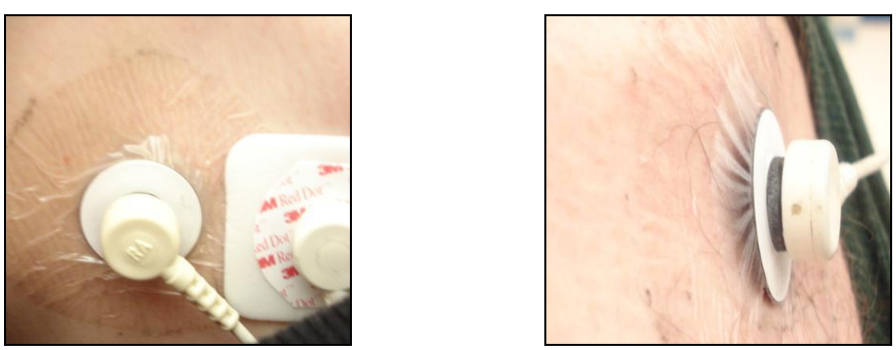

Figure 5: Dry Electrode Adhesive Issues

CHAPTER V

SUMMARY AND CONCLUSIONS

SUMMARY

The purpose of this study was to investigate if differences in signal quality, reflected by the signal-to-noise ratio (SNR), existed between two different electrode types over a 96 hour period of continuous wear. The conventional wet electrode that is commonly used in clinical and research settings is associated with numerous disadvantages due to its reliance on the wet component (i.e. electrolytic gel) of the electrode. Some disadvantages include skin irritation, electrolyte gel dehydration, and electrode expiration. 3[,11,12,17,18,23,25,26] The use of a dry electrode, which does not rely on an electrolytic gel, may therefore circumvent many of the aforementioned disadvantages associated with the wet electrode. This investigation specifically concerned an assessment of the standard gel 3M™ Red Dot™ 2560 electrode and the Orbital Research Incorporated (ORI) dry electrode. From a clinical and research perspective an investigation of the signal quality of the two different types of disposable electrodes was necessary as the accuracy of the ECG signal is the primary concern. Therefore signal quality was compared between the wet and dry electrodes throughout the length of wear. Also, the potential application of either electrode in situations that require extended duration monitoring was of value. Therefore, a second and third hypothesis was formulated concerning the comparison of potential deterioration within each electrode throughout the length of wear.

The results revealed that no significant differences existed within the dry electrode mean SNRs over time, therefore, indicating that the signal quality did not deteriorate. Although a significant difference was observed within the wet electrode's mean SNRs between the baseline day (day 0) and day 1 in the initial Standing stage of testing, the noise was reduced; therefore, the signal did not deteriorate, or worsen over time. The hypotheses for each of the aforementioned were therefore accepted. A significant difference was observed between the wet and dry electrode SNRs during the Supine stage only. Differences between the two electrodes on days 2 and 4 in the Supine stage favored the wet electrode. The hypothesis for the aforementioned was therefore rejected. Concerning subjective information, the main effects of extended electrode use, "itchiness" and redness at removal site, impacted the subjects similarly and was not dependent on electrode type. Other effects were non-permanent, such as indentations at the sites of the dry electrodes and minor bruising of the skin under the electrode site.

CONCLUSIONS

Signal quality did not significantly deteriorate over time for either the wet or the dry electrode. Although a more favorable SNR was observed for the wet electrode during the Supine stage, this most likely would not be reflected clinically. It may be reasonable to suggest that clinical significance supersedes statistical significance based on SNR, therefore, a more qualitative analysis may be needed for further clarification.

Application

Although the electrodes appear to have performed similarly, the dry electrode may be better suited for use as it does not experience the wet electrode's detriments. Suggested applications of the ORI dry electrode includes both acute and chronic use (up to 96 hours) for ECG monitoring during rest and ambulatory situations.

Limitations

The most noteworthy limitation concerned the lack of consistency between the adhesives used. The wet electrode had a foam adhesive, whereas the ORI dry electrode had a translucent film adhesive. Because the adhesive used was inconsistent between electrode types, it is difficult to assert that the electrode's performance was not affected by the material used to adhere it to the skin. Various limitations concerned the subjects involved in the study. The subjects utilized were both convenient and fairly homogeneous in age and race. Sample size (n=20) was also small. Utilizing more subjects and a more heterogeneous group of subjects would increase the generalizability of the results. Also, information was not provided concerning the cost of the ORI dry electrode; therefore it is unknown whether the cost of the ORI dry electrode is prohibitive.

Future Research

Future research may concern differentiating between statistical and practical significance of SNR ECG data. Reports concerning both aspects will rely more heavily on the participation of a clinician. Data may then be assessed statistically by the researcher and qualitatively by the clinician. It may be appropriate to report data assessed qualitatively with an associated discussion of percent readable or usable ECG traces versus unreadable or unusable. Future research may also concern the utilization of different adhesive tapes. The adhesive tape associated with the dry electrode demonstrated problems during long-term use. The use of another adhesive may create a more robust contact between the electrode and the skin over extended periods of wear. Additional research may also investigate the potential to expand the dry electrode's monitoring capability to other biopotential signals (i.e. EEG, EMG, etc.). The appropriateness of the use of the ORI dry electrode in other activities of various intensities should also be investigated.

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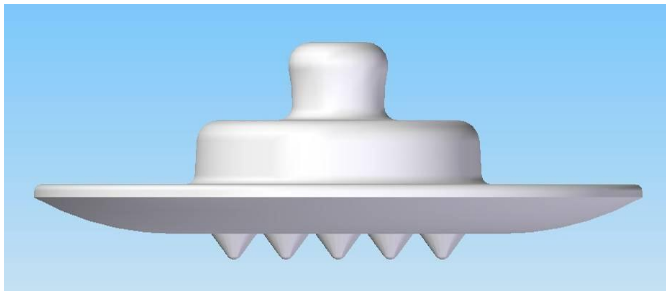
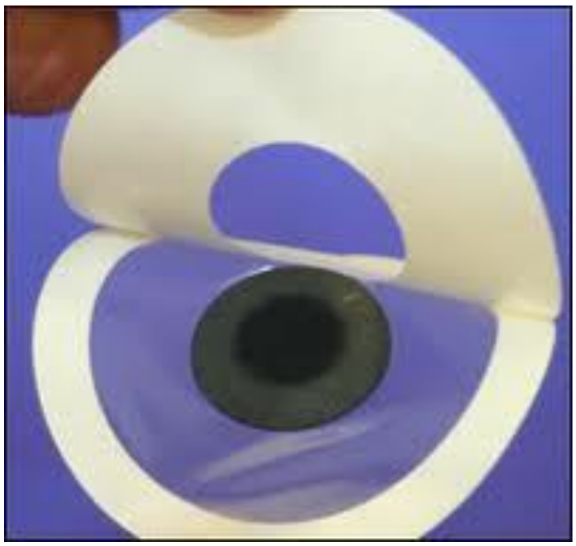
APPENDICES

APPENDICES

Appendix A: Orbital Research Incorporated (ORI) dry electrode with micro-features used in this study (ORI, Cleveland, OH)



Electrode micro-features shown



Electrode attached to clear adhesive tape

Appendix B: Orbital Research Incorporated (ORI) dry electrode with micro-penetrators used in previous research[18] (ORI, Cleveland, OH)

Electrode micro-penetrators shown

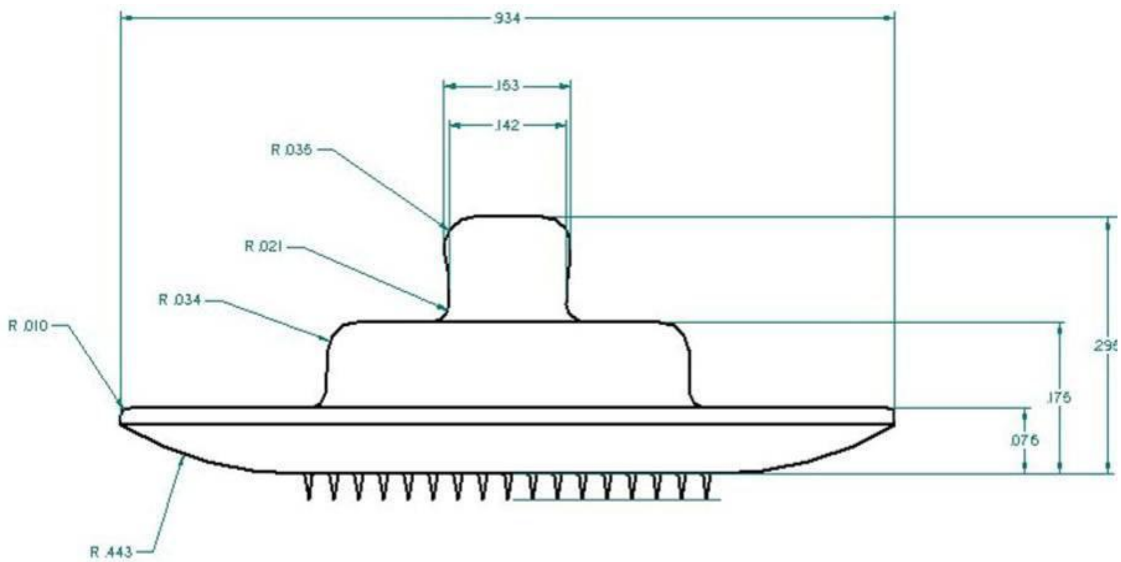


Diagram: Electrode micro-penetrators

Appendix C: 3M™ Red Dot™ 2560 electrode (3M, St. Paul, MN)

Appendix D: Recruitment Flier

Cleveland State University

Study Participants Needed!

CSU Human Performance Lab needs volunteers (18-55 years-old) who can participate in a research study on comparing two types of ECG electrodes worn over several days.

Study involves walking on a treadmill four days in a row while being monitored for a time of 18 minutes each day.

Monetary Compensation

If interested please email

k.sparks@csuohio.edu

or call

(216)687-4831

Appendix E: Informed Consent

Informed Consent for Participation
Clinical comparison of Orbital Inc. dry electrodes to the clinical standard electrodes

INTRODUCTION

You have been asked to participate in a research study to be conducted in the Human Performance Laboratory at Cleveland State University. The purpose of this study will be to measure the deterioration of signal quality using two different types of electrodes (ORI dry electrode and gel-based 3M™ Red Dot™ 2560 electrode) worn over four days (96 hours).

The significance of this study is to indicate if the use of a dry electrode (without electrolyte gel) can be as effective in providing useful ECG traces collected in clinically typical paradigms relative to accepted and standardized electrode technologies.

The impact of the study is that a new electrode can be validated and then deemed efficacious. The ORI electrode technology may change ambulatory ECG testing protocols based on the ability to maintain signal quality over time without the use of electrolyte gels for conductance of signal, that are sometimes irritable to skin.

PROCEDURES

After undergoing a resting ECG, you will perform a standard sub-maximal (85% of predicted maximal heart rate) graded exercise test (GXT) on a motor driven treadmill, using standard protocol of the Human Performance Laboratory. Each GXT shall be regarded as one trial. You will be asked to complete 5 trials; one trial at day 0 is to obtain baseline data and again every 24 hours for four days. Each test session should only take approximately 20 minutes per day with the total time being approximately 90 minutes. Performance of the ORI electrodes will be directly compared to the standard electrodes. Both types of electrode will be worn side-by-side for comparison. You will wear the two electrodes for 96 hours and return to the laboratory to be retested for the subsequent trials.

RISKS AND DISCOMFORTS

The probability of risk to you is low. The potential risks include minor skin irritation and/or discomfort after days of wearing the electrodes.

The dry electrodes will not be re-used between patients. During exercise testing, there exists the possibility of certain physiological changes, including abnormal blood pressure, fainting, heart arrhythmia, and in rare instances heart attack, stroke or death (1:20,000 exercise tests). Every effort will be made to minimize these risks.

There are no anticipated benefits for you as a subject other than you will be compensated for your participation. However, your participation will help acquire knowledge for the development of the use of a more convenient electrode.

CONFIDENTIALITY
To protect your privacy and confidentiality, your name will not be used in any documentation of the project. The information, however, will be used for a statistical or scientific purpose with your right of privacy retained.

PARTICIPATION
I understand that participation in this project is voluntary and that I have the right to withdraw at any time with no consequences. I understand that if I have any questions about my rights as a participant, I can contact Cleveland State University's Institutional Review Board at 216-687-3630.

I attest and verify that I have no known health problems that could prevent me from successfully participating in the sub-maximal graded exercise test.

INQUIRIES
Any questions about the procedures used in this project are welcome. If you have any doubts or questions, please ask for further explanations or call Dr. Kenneth Sparks at 216-687-4831.

PATIENT ACKNOWLEDGEMENT
The procedures, purposes, known discomforts and risks, possible benefits to me and to others have been explained to me. I have read the consent form or it has been read to me, and I understand it. I agree to participate in this program. I have been given a copy of this consent form.

Signature ______________________________________ Date____________
Witness ______________________________________ Date ____________

Appendix F: Post-Experimental Period Subjective Reporting/ Researcher Observation

Wet Electrode (out of 20 Subjects)	
Electrode-induced annoyance*	13
Redness at electrode site	13
Bruising at electrode site	1
Dry Electrode (out of 20 Subjects)	
Electrode-induced annoyance*	16
Redness at electrode site	15
Bruising at electrode site	13
Broken skin at electrode site	1
Skin indentations at electrode penetrator sites	20
RA Electrode Site (out of 20 Subjects)	
Site that induced more irritation	2
Bruising at the site of the dry electrode penetrators	4
LL Electrode Site (out of 20 Subjects)	
Site that induced more irritation	7
Bruising at the site of the dry electrode penetrators	9
Bruising at wet electrode site	1

*Annoyance was most commonly reported as "itchiness"

RA: Right arm electrode site; LL: Left leg electrode site